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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/740,075
Filing Date: December 17, 2003
Appellant(s): RENSHAW ET AL.

J. Cooper McDonald
For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed on June 22, 2009 and the Supplemental Appeal Brief filed on August 26, 2009 appealing from the Office action mailed August 20, 2008.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims.

The statement of the status of claims contained in the brief is incorrect.

A correct statement of the status of the claims is as follows:

This appeal involves claims **1-3, 5, 7-20 and 22-26**.

Claims **1, 12, 17 and 22** were amended subsequent to the final rejection.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on June 16, 2009 has been entered.

(5) Summary of Claimed Subject Matter.

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal.

The appellant's statement of the issues in the brief is correct.

(7) Claims Appendix.

The copy of the appealed claims contained in the Appendix to the brief at pages 34-38 is correct.

(8) Evidence Relied Upon.

The following is a listing of the evidence (e.g. patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number	Name	Date
6,103,703	Renshaw	04/27/1999

Beers et al. (eds.), "Sleep Disorders," Chapter 173 in The Merck Manual of Diagnosis and Therapy, 17th Edition, Merck & Co., Inc., Rahway, NJ, January, 1999, only title pages and text pages 1409-1414 supplied. (PTO-892 ref. **W**).

Pugh et al. (eds.), Stedman's Medical Dictionary, 27th Ed., Lippincott, Williams & Wilkins, 2000, Philadelphia, PA, see the definition of "insomnia" bridging pages 906-907. (PTO-892 ref. **X**).

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims.

(9.01) Ground of Rejection: 35 U.S.C. §112, First Paragraph (Enablement).

Claims **1-3, 5, 7-20 and 22-26** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

Summary of the Rejection:

Examiner has inspected the disclosure and Figures 1 and 2, and finds therein what appears to be data concerning the reactions to the administration of CDP-choline by a single human host, apparently a 33 year old subject who appears to be addicted to or habituated to, alcohol, cocaine and/or tobacco and who consumes caffeinated beverages, a possible additional habituation. Applicant has claimed broadly the treatment of sleep deprivation with some identified causes in all human and mammalian hosts, but has not provided sufficient exemplifying data to adequately enable such a broad scope of claimed subject matter. Examiner suggests that Appellant needs to establish individually the effective treatment of specific sleep related disease conditions (insomnia, narcolepsy, etc. etc.) by testing appropriate groups of subjects (night shift workers, interns doing 24 hour stints, etc.). Alternatively examiner suggests Appellant may elect to demonstrate the effective treatment of specific-drug addicted hosts who suffer from sleep deprivation(s). In any event the instant data set is simply inadequate to enable use of the instant claimed methods of treatment because of the lack of adequate showing(s) that the claimed effects of CDP-choline administration are common to a reasonable number of similarly situated mammalian hosts in need of such treatment.

Detailed Analysis by Application of the Wands Factors:

A. The breadth of the claims: The breadth of many of the claims is excessive because of the presence of generic terms including "treating a sleep disorder" (claims **1, 12 and 22**) and "increasing cognitive function" (claim **17**).

B. The nature of the invention: The instant invention is directed to a method of treating sleep or sleep-related disorders as most broadly defined in claim **1**, and more specifically defined in claims **13-14** (substance abuses), in claim **15** (constructive or obstructive sleep apnea, restless leg syndrome, periodic limb movements, or narcolepsy), in claim **20** (problem sleepiness), and in claim **25** (restless leg syndrome, periodic limb movements, or narcolepsy).

C. The state of the prior art: The administration of CDP-choline is associated in some prior art references with the effective amelioration of insomnia, particularly in elderly hosts. See the prior art-based rejections below.

D. The level of one of ordinary skill: The skill level of the ordinary practitioner is hard to access because, while testing for efficacy in the treatment of insomnia or a similar symptom is well established in the prior art, said testing has not been applied herein to the medicinal effect(s) of any substance other than one test of CDP-choline on a host suffering from multiple dependencies. So, while the skill level for the ordinary practitioner is established for the single unique example disclosed herein, there is no exemplification-based guidance for any other type of host (e.g. a host suffering from a single sleep disorder apparently induced to occur by a single cause), or guidance directed to and based on the individual effect(s) of any one of the numerous other active ingredients listed in claim **1**.

E. The level of predictability in the art: The art of treating sleep disorders is highly variable in its predictability because of the large array of different causes or circumstances under which it has been observed to occur, both known (drugs, shift work, etc.) and inadequately established or unknown ("aging," pain, physical injuries, etc.).

F. The amount of direction provided by the inventor: Referring to Figures 1 and 2, it appears that Appellant has only tested the administration of CDP-choline on a single human host who is apparently afflicted with multiple chemical dependencies including dependencies on alcohol, cocaine and/or caffeine.

G. The existence of working examples: There appears to be only a single working example and no clear indication discernable by examiner concerning what individual or particular sleep disorder or disorders has been or have been effectively treated in this particular host.

H. The quantity of experimentation needed to use the invention based on the content of the disclosure is deemed to be excessive in light of the indefinite and functional claim terminology rendering the relevant claim's scopes indefinite, and because the exemplary supporting evidence and associated guidance is so limited in quantity, making extrapolation to the treatment of sleep disorders in other hosts a very uncertain proposition. As a consequence the minimum necessary guidance concerning how to use each of the various different active ingredients as listed in claims **1, 12, 17 and 22**, and their particular application to any one of the various different sleep disorder treatments, is simply absent.

(9.02) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **1** at line 3 the term "a compound comprising" is indefinite because the subsequent list of compounds are all named as separate compounds rather than substituent moieties of a larger molecular species, and because the larger molecular species implied by the term "comprising" (including) is not subsequently defined thereby leaving the metes and bounds of the claimed subject matter incompletely defined. See also claims **12, 17 and 22** wherein the same problem reoccurs.

(9.03) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **12** at lines 4-5, the term "is not compromised by an existing physical condition" is an improper negative limitation because the particular "existing physical limitation[s]" has/have not been specified in the claim.

(9.04) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **13** the term "said sleep disorder is caused by a substance abuse disorder" lacks proper antecedent basis. Examiner suggests introduction of the term -- further comprising -- in order to effectively address this expansion of the subject matter definition of claim **12**. Said term also renders the claim incomplete because the particular "substance abuse disorder" has not been specified. See also claim **23** *in re* its dependence from claim **22**: the same error reoccurs in claim **23**.

(9.05) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **19** the term "not caused by a substance abuse disorder" renders the claim incompletely defined because the particular substance abuse disorder(s) has(have) not been specified.

(9.06) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **1**, at lines 1 and lines 7-8, appears to be self-contradictory because "normalizing the sleep/wake cycle in a mammal" has been alleged in the claim to not include "insomnia." According to Stedman's Medical Dictionary (27th Ed., Lippincott, Williams & Wilkins, Pugh et al. (eds.), 2000, Philadelphia, PA, see pages 906-907: PTO-892 ref. **X**), "insomnia" is defined as

> "inability to sleep in the absence of external impediments ... during the period when sleep would normally occur; may vary in degree from restless or disturbed slumber to a curtailment of the normal length of sleep or to absolute wakefulness."

In addition Appellant is referred to **Beers et al.** (Merck Manual; PTO-892 ref. **W**) wherein the subject of "insomnia" is dealt with in greater detail including medical advise concerning substances well known to be effective in inducing sleep. Examiner does not understand how Appellant can justify or otherwise explain the obvious contradiction in terms presented by Appellant in claim **1**, and the same or similar contradictions in the remaining independent claims **12, 17 and 22**. The unanswered question is "How can one of ordinary skill effect 'normalizing the sleep/wake cycle' as required by the preamble of claim **1** and not treat 'insomnia' as defined by these two references but as required by the terminal limitation of claim **1**?"

(9.07) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claim **1, 12, 17 and 22** the terms "normalizing the sleep/wake cycle," "treating a sleep disorder" (claims **12** and **22**), and "increasing cognitive function in a sleep-deprived mammal" are each insufficient to adequately define the particular disease condition being treated and thereby each noted term renders the associated claim incompletely defined. The above noted terms each represent a description of a therapeutic goal (a sleep-disorder-related symptom to be treated), but said terms do not define with particularity a critical portion of the subject matter (disease to be treated) being claimed.

(9.08) Ground of Rejection: 35 U.S.C. §112, Second Paragraph.

In claims **17** and **20** the method of treating "problem sleepiness," a condition not described with this term in either of examiner's two medical dictionaries or in The Merck Manual, 17th Edition, appears to be synonymous with a method of treating "narcolepsy." Clarification of the intended content of claims **17-20** is respectfully requested.

(9.09) Ground of Rejection: Obviousness-type Double Patenting.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-3, 5, 7-20 and 22-26** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-16*** of U. S. Patent No. **6,103,703** (PTO-1449 ref. **A10**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment, directed to "increasing cognitive functions in a sleep deprived mammal," "treatments of insomnia-like disorders," or other "cognitive dysfunction[s]" appear to be included within the scope of "ameliorating a stimulant induced disorder," a term found in the preamble of claim **1** of the **'703** patent In addition the alleged active ingredients are selected from an overlapping list of allegedly active compounds including a cytidine-5'-nucleotide or a 2'-deoxycytidine-5'-nucleotide, are directed to substantially overlapping subject matter. See the **'703** reference at claim ***15*** wherein the administration of CDP-choline is specifically noted as an active ingredient in a claim limitation.

(9.10) Ground of Rejection: Obviousness under 35 U.S.C. §103(a).

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-3, 5, 7-20 and 22-26** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Renshaw et al. '703** (PTO-1449 ref. **A10**: U. S. Patent No. **6,103,703**).

The instant claimed methods of treatment include "treating a sleep disorder" including disorders caused by stimulants or depressants including "alcohol," "caffeine" and "cocaine," "increasing cognitive functions in a sleep deprived mammal, or other cognitive dysfunction by the administration of a compound selected from extensive listings in claims **1, 12, 17 and 22** wherein these listing all include cytidine, cytidine-5'-nucleotides, and 2'-deoxycytidine-5'-nucleotides, including the sole exemplification wherein CDP-choline is administered.

The **'703** reference claims the "ameliorating a stimulant induced disorder," wherein the "stimulant" is defined in claim ***13*** as "cocaine" and wherein the treatment comprises administration of a cytosine or cytidine compound including CDP-choline or CDP. The "cocaine is specifically named as a causative agent/stimulant of the condition to be treated in instant dependent claims **14 and 24** and is only generically excluded by instant dependent claim **19**, meaning that nearly all of the instant claims overlap with the language of the **'703** patent claims. The claimed subject matter in the **'703** reference is not identical with the subject matter in the instant application, but also overlaps therewith in light of the common stimulant and common active ingredients administered, thereby rendering the instant claimed subject matter obvious.

Therefore, the instant claimed methods of treating sleep-related disorders by the administration of cytosine, cytidine, a cytidylate nucleotide, or CDP-choline to a host in need thereof would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

New Ground of Rejection.

This Examiner's Answer does not contain any new ground of rejection.

(10.01) Response to Argument: 35 U.S.C. §112, First Paragraph (Enablement).

Beginning at page 6 of Appellant's Brief, citing the MPEP at §2164.04, Appellant argues that the necessary and sufficient " ... evidence or reasoning has not been provided by the Examiner to support the rejection of the present claims," and in the subsequent heading and following text argues as follows "I. the present claims are enabled by the specification"(bold face and capitalization not provided). Examiner respectfully disagrees, and cites in opposition the MPEP at §§2107.01(IV)-2107.04 wherein the standards for enablement to be applied to claims directed to medicinal treatment are elucidated and include a discussion of the relationship between 35 USC §101 utility rejections and 35 U.S.C. §112, first paragraph, enablement rejections. The instant rejection is asserted based on examiner's conclusion that the instant claimed subject matter lacks adequate enabling support because, while a single exemplification has been provided, this single example does not provide sufficient basis for extrapolation of that single positive result to any other mammalian host(s) wherein only one of the causes identified herein is present. Therefore, while examiner did not make a rejection alleging lack of utility because utility has been shown for one active ingredient administered to one host, the question of whether there is sufficient guidance to practice the instant claimed invention. The guidance necessary to practice the treatment of sleep disorders in other hosts by the administration of other untested active ingredients wherein different single or multiple causes may be present is simply absent from the instant file history. For this reason Examiner concludes that the instant claims represent incompletely enabled subject matter.

The unenabled portion of the claimed subject matter has been found to resemble the completely unenabled subject matter of *Ex parte Balzarini* (21, USPQ 2 1892, 1894 (1991), *Balzarini* is a case wherein both an enablement rejection and a utility rejection were upheld by the USPTO BPAI (see "OPINION - REJECTION I" and a related footnote at the bottom of page 1894), therefore supporting citation thereof herein as an opinion that is closely analogous to the instant enablement rejection.

Appellant then asserts in the paragraph bridging pages 7 and 8 that "[t]he present invention is based on the discovery that citicoline [aka cytidine diphosphate choline or CDP-choline] is useful for the normalization of the sleep/wake cycle and improves the quality of sleep and mood." This assertion represents the above noted "extrapolation" of a single experimental exemplification to a generic treatment, an extrapolation that, in Examiner's respectfully advanced opinion, is not based on adequate evidence, and therefore has been found to be lacking in adequate exemplification-based support.

At page 8 of the Brief, beginning at line 3, Appellant then engages in speculations concerning how the single experimental result provided may be imagined to enable other prospective embodiments, wherein the term "prospective" means that the examples have not been confirmed by and scientifically supported by specific experimental results.

Appellant then again argues beginning at page 9 (next to last sentence in the paragraph labelled "II.") of the Brief that " .. the basis for the rejection is Examiner's unsupported belief that Appellant has not provided sufficient data to support the claimed scope." This statement is incorrect because examiner has provided in the rejection, and herein, clear reasoning in support of the rejection at issue, and has cited a relevant judicial opinion including guidance that supports a similar conclusion in a similar situation (*Balzarini*).

In paragraphs beginning at the bottom of page 9 of the Brief Appellant asserts incorrectly that "Examiner misapprehends the burden on the Office by raising such a rejection," an assertion that appears to be an attempt by Appellant to avoid acknowledgement of the burden of the law (35 U.S.C. §112, first paragraph) on Appellant when medical treatment claims are presented for examination. Appellant than again argues on the basis of the basis of the above quoted false premise that Examiner has failed to meet the burden of the Office.

Appellant then argues that the citation of *Balzarini* is inappropriate because the first "Opinion" in the case only upholds the rejection made under 35 U.S.C. §101 alleging lack of utility. Appellant's assertion is factually incorrect. Examiner refers Appellant to *Balzarini* at page 1894, footnote 2, wherein the BPAI states that "[w]hile the examiner has presented these rejections [a 101 utility rejection and a 112, first paragraph, enablement rejection] separately in the Examiner's Answer, we have combined them for consideration in this appeal since they present similar issues." Appellant then argues at page 11 of the Brief that " ... while a rejection for lack of utility was upheld by the Board in *Ex parte Balzarini*, that case involved a rejection supported by scientific evidence in the form of published references indicating that the claimed methods were inoperable" and that "[n]o such evidence has been provided in the present application." Appellant is arguing that Examiner must prove both a false assertion and a straw man negative, i.e. that *Balzarini* only stands in its first opinion for a 101 rejection being upheld, and that the instant rejection asserts that claims are not patentable on the basis of scientific evidence that has not been provided. Although the MPEP does not so state, the first Opinion in *Balzarini* is directed to one decision that deals with two issues simultaneously. The

two issues are "utility" and "enablement" as noted above in a footnote quotation from the actual decision. And Examiner is unaware of any legal requirement that arguments in support of the 112, first paragraph enablement requirement require scientific evidence of inoperability to support a rejection alleging lack of adequate enabling support.

Response to Appellant's Criticism of the Wands Analysis.

At page 12 of the Brief, Appellant argues that a *Wands* analysis in re **Breadth of the Claims** requires a finding of fact, and then argues that the criticism of excessive breadth of "generic" terms in the claims is not a finding of fact. Appellant then claims that Examiner has not provided any appropriate precedent (Appellant's misreading of *Balzarini* and the MPEP's incomplete analysis of *Balzarini* have been noted above), and than argues that Examiner has failed to address the generic term "normalizing the sleep/wake cycle" found in instant claim **1**.

Although Examiner has not specifically addressed the term "normalizing the sleep/wake cycle," Examiner has repeatedly referred to the general subject matter of the instant claim set throughout the *Wands* analysis. Examiner has provided precedent that is clearly applicable. And lastly, Appellant's analysis of the disclosure in the paragraph bridging pages 12 and 13 of the Brief fails to acknowledge the distinction between specific embodiments actually carried out and embodiments that are prospective and therefore makes a misleading criticism of the rejection. Comparison of claim breadth with the quantity of specific embodiments actually carried out is a critical component of enablement analysis, a component that is apparently not considered relevant to the instant debate in view of Appellant's failure to address this key issue in the *Wands* analysis of claim breadth.

At page 13 of the Brief, Appellant's analysis of Examiner's description of the "**Nature of the Invention**" appears to be equivocal. Appellant initially appears to have agreed with Examiner's analysis, and then seems to have disagreed with said analysis.

It is Examiner's detailed view that the independent claims are generic to methods of treating various sleep disorders by the administration of "apparently" a single active ingredient selected from an alternative listing thereof in claim **1** and also listed in claims **12, 17 and 22**. Examiner has used the term "apparently" because the claims do not define the active ingredients narrowly, but claim administration of "a compound comprising cytidine, ...[etc.]" as the process step, a term that invites speculation concerning whether either unspecified

combinations of listed ingredients and/or unlisted additional active ingredients, or combinations thereof are intended by Appellant to be "included" within the scope of the claimed subject matter. The disorders claimed to be effectively treated, and specific treatment goals, are defined both generically and specifically throughout the claims.

In claims **1 and 2** the "normalization of the sleep/wake cycle" is treated in order to achieve one of the following results: "reduced fatigue or tiredness," "increases wakefulness," or "improves the sleep quality of ... [a] mammal."

Claims **12-15** are directed to "a method of treating a sleep disorder ... not compromised by an existing physical condition" and "wherein said mammal is not suffering from insomnia." Said "disorder" is further defined in claim **13** to be caused by "a substance abuse disorder" that is further limited in claim **14** to the abuse of "alcohol," "caffeine," or "cocaine." Alternatively said disorder is further defined in claim **15** as "constructive or obstructive sleep apnea," "restless leg syndrome," "periodic limb movements," or "narcolepsy." In claims **19-20** the "sleep disorder" of claim **12** is alternatively defined as "not caused by a substance abuse disorder," (emphasis added), or in claim **20** wherein said "sleep disorder" is further defined as "problem sleepiness."

Claims **17-18** are directed to "[a] method of increasing cognitive function in a sleep-deprived mammal" and "wherein said mammal is not suffering from insomnia."

Claims **22-26** are directed to the treatment of a "sleep disorder" and "wherein said sleep disorder is not insomnia or sleep apnea," wherein said "disorder" (emphasis added) is further defined in claim **23** to be caused by "a substance abuse disorder" that is further limited to the abuse of "alcohol," "caffeine," or "cocaine" in claim **24**, or said disorder is further defined in claim **25** as "restless leg syndrome," "periodic limb movements," or "narcolepsy."

In conclusion, the breadth of the claims was found by Examiner to be excessive because the experimental support for efficacy of treatment is limited to a single example wherein a single human subject simultaneously suffering from multiple symptoms has been treated by administration of an effective dosage(s) of CDP-choline, a circumstance that has not herein been dissected, either experimentally or statistically, to establish that extrapolation to the treatment of any single symptom, or to achieve any single therapeutic result, is reasonably likely to occur. The minimal experimental support provided by the single specific

exemplification noted above, and the consequential absence of an adequate quantity of guidance supports the conclusion that undue experimentation would be necessary to effect the practice of most if not all elements of the claimed invention.

At pages 14-15 of the Brief, Appellant has argued in opposition to examiner's analysis of **The State of the Art** and notes that previous Office actions have cited other prior art, wherein said prior art is now withdrawn in view of amendments or arguments prior art (listed in applicant's comments). Appellant then argues that " ... Examiner has not provided a single reference calling into question the feasibility of normalizing the sleep/wake cycle, ... or the feasibility of using any of the compounds recited by the present claims." The term "feasibility," defined in Webster's Dictionary as meaning "capable of being done or carried out," implies that Appellant is making an incorrect or beside the point argument because "feasibility" implies that a utility rejection under 35 U.S.C. §101 is being argued against, or that Appellant is again referencing the previous misreading of the *Balzarini* Board decision. Examiner notes that the rejection of record, devised in reliance on the *Wands* factors, cites the issue of "lack of adequate enablement," not "lack of utility." In conclusion, Appellant appears to be arguing in favor of patent claims as if they are a "research proposal," but has not been arguing in favor of the "patentability" of the instant claim set. Examiner reminds Appellant of the teachings of *Brenner v. Manson*, 148 USPQ 689 (S. Ct. 1966), wherein the Supreme Court teaches that a patent is awarded for a successful exploration already accomplished, and is " ... not a hunting license."

On the issue of "**The Level of one of Ordinary Skill**" Examiner admits that the previous statement in the rejection of record was excessively brief. This portion of the rejection provided above has been amended in order to more accurately and completely address this issue from Examiner's perspective.

Appellant addresses this issue by arguing that an ordinary practitioner in the instant art would be either a Ph.D. medicinal chemist or an M.D. and can then be assumed to " ... have a high level of skill in the pharmaceutical arts." Examiner disagrees in part, noting that the chemical arts and the pharmaceutical arts represent a very small part of medical education and therefore that MD's cannot be reasonably assumed to " .. have a high level of skill in the pharmaceutical arts." Appellant then digresses into a discussion of the contents of the disclosure, a discussion that fails to note the difference between examples that have been

reduced to practice and examples that are only prospective, and Appellant has also failed to note the minimal presence of the former type of example in the disclosure. Appellant concludes with the presumption that the prospective exemplifications, in the presence of a single equivocal reduction to practice, constitute a disclosure that is sufficient to avoid the need for undue experimentation. Examiner respectfully disagrees with this conclusion because Appellant is in effect asserting that a single equivocal exemplification can be the basis for a competent extrapolation to all of the various listed active ingredients as effectively administered to treat all "sleep disorders: including the various "sleep disorders" explicitly listed in the instant claim set. Without the provision of adequate additional guidance that would accompany the provision of relevant additional test data, the instant claims encompass subject matter that far exceeds the metes and bounds of subject matter adequately enabled by the instant disclosure.

For these reasons Examiner finds that the asserted extrapolation can not be reasonably carried out without resort to undue experimentation.

Beginning at page 15 of the Brief, in commenting on Examiner's analysis of "**The Amount of Direction Provided by the Inventor**" Appellant argues that " ... Examiner has confused 'direction' with experimental data." Appellant has argued, as above, that the human test data discloses in Figures 1 and 2 is properly supplemented by the prospective disclosures of "compounds," "specific disorders," and "preferred dosages," apparently proceeding on the assumption that the ordinary practitioner is free to extrapolate at will even in the area of medicinal methods of treating diseases and disorders that implicate the operation of the mental/nervous system circuits of human and other mammalian hosts. Appellant's assertion that " ... nothing more is required" is respectfully disagreed with because the amount of "Direction Provided by the Inventor" is presently insufficient to determine whether any single "sleep disorder" can be effectively treated by the administration to a mammalian host in need thereof an effective amount of any single active ingredient presently listed in the claims. Appellant appears to be again arguing in favor of the granting of a "hunting license."

At page 16 of the Brief, in Appellant's arguments in response to Examiner's analysis of "**The Existence of Working Examples**," Appellant's summary of Examiner's analysis at lines 1-7 is a fair summary, but then Appellant asserts " ... disagree[ment] with Examiner's conclusions." Appellant then argues that " [t]he data of Figure 1 is directed to the quality of

sleep for multiple subjects," an argument that appears to be uncorroborated by any portion of the noted Figure or legends therein, or the remarks describing same in the Brief Description of the Figures at page 5 of the disclosure. In addition, Examiner has not located any data set(s) wherein the calculation of the data in Figure 1 has been set forth or has been summarized, or where the statistical error analysis leading to mathematical determination of the error bars displayed in Figure 1 has been presented as part of the original disclosure or in a supplemental submission. Therefore, Appellant's assertions *in re* the meaning of Figure 1 are not found to be factually accurate at this time.

At page 16 of the Brief, second full paragraph, last sentence, Appellant discloses that although " ... the subjects of the experiments reported in Figures 1 and 2A-2B were users of cocaine, Appellant also submits that the results of CDP-choline [administration] on the sleep/wake cycle and [the] quality of sleep are applicable to individuals who are not users of cocaine." Examiner notes Appellant's submission, and also notes that Appellant's submission is lacking support from any experimental data establishing the validity of the asserted extrapolation to the effective treatment of any specific "sleep disorder(s)" in non-cocaine users. Again Appellant is respectfully requested to note the above quotation of *Brenner v., Manson* and the conclusion therein that patents are not to be awarded as if they are analogous to a "hunting license."

At the bottom of page 16 of the Brief, Appellant argues that they have " ... provided working examples and explanations of their relevance." This is an incompletely supported conclusion that Examiner respectfully disagrees with because there is a clear disagreement stated above concerning the number of working examples disclosed herein and the degree of enablng support provided thereby. In addition, at the top of page 17 of the Brief, Appellant, following a quotation of the appealed Office Action excerpted from page 2, argues that "[t]he Examiner has not, however, supported this conclusion [of insufficient evidence] with legal or scientific analysis as required." Examiner respectfully disagrees, noting repeated suggestions made by Examiner during prosecution that Appellant might achieve a patent when appropriate additional data was made of record. These suggestions have not been addressed by the submission of any additional data from Appellant. In the first full paragraph at page 17, Appellant argues that "[t]here is no better indicator of the enablement of the present claims than the demonstrated efficacy in humans," a misleading statement because while Examiner has not questioned the data per se, Examiner has questioned the inadequate quantity and

inadequate breadth of the data, and has found that Appellant's failure to effectively address these inadequacies is the reason why the instant rejection has been maintained.

At page 17 of the Brief, second full paragraph, last two sentences, Appellant argues that the instant rejection in effect requires "a clinical trial," then suggests that the rejection is in part for "lack of utility," and finally asserts that claims in the instant subject matter area do not require support from "experimental data of any kind." Examiner respectfully disagrees with all three assertions, noting that Appellant is correct that clinical trials are not required, noting that the question of utility has already been dealt with above, and lastly, that the question of the requirement for a minimum quantity of relevant experimental data is well established (see MPEP at §2107.01(IV): "112, first paragraph addresses matters [including] ... whether the claims are fully supported by the disclosure," "whether the Appellant has provided an enabling disclosure," etc.).

And in the paragraph bridging pages 17 and 18 of the Brief, Appellant argues that the prospective disclosures found in the specification are an adequate basis for enablement herein, an assertion dealt with repeatedly above.

At pages 18-20 of the Brief, Appellant again argues *in re* the issue of "**Undue Experimentation**" that Examiner has failed to make any findings of fact. This assertion follows statements by Appellant that
i) the Examiner had found that the claims were flawed because of the presence of both indefinite terms and functional terminology that adversely effected analysis of claim scope, and
ii) that Examiner had also found that the enablement of the claims was in doubt because of the absence of sufficient data to provide the ordinary practitioner with the guidance necessary to practice the invention as claimed. The inconsistency of Appellant's arguments has again been illustrated.

Appellant then argues that the human test data of record plus what Appellant characterizes as "scientific reasoning to support the scope of the claims" is sufficient at present as a basis for finding the claims enabled. Appellant further asserts that the standard for enablement has been supported by the prospective disclosure of test protocols, of lists of compounds, and of formulations that Appellant presumes are likely to be effective, and prospective hosts which Appellant also presumes to be likely to be effectively treated therewith

for "sleep disorders." Appellant also presumes that " .. dosage [determination] for treating a particular condition is routine once the lead compounds are identified." Following this repeatedly conclusory analysis, Appellant asserts that the instant disclosure and associated case file history has " ... provided a reasonable amount of guidance with respect to the claimed methods." Examiner respectfully disagrees. Appellant has argued that because the instant disclosure advances Figures 1, 2A and 2B as being directed to experimental data concerning the effect of a single compound, CDP-choline, on an unknown number of cocaine-habituated test subjects (Figure 1) and the effect of the same compound on a single subject apparently simultaneously habituated to cocaine, alcohol, and caffeine (Figures 2A and 2B). Appellant repeatedly argues that extrapolation of the test data provided herein to "untested" compounds administered for the treatment of hosts suffering from other untested symptoms causing various kinds of other "sleep disorder[s]" is permissible in the absence of adequate test data to permit the ordinary practitioner to have advance knowledge concerning how to practice these alternative methods of treatment. Again Appellant appears to be arguing that a patent should be considered to be analogous to a "hunting license."

Beginning at page 19 of the Brief, Appellant argues separately that certain dependent claims are separately enabled

Examiner concludes that Appellant may have uncovered a method of treating "sleep disorders" of the types generically and specifically claimed herein by administration of any one of the specifically named compounds listed in an independent claim, but that Appellant has failed thus far to provide a sufficient evidentiary basis to enable the entire breath of the claimed subject matter. For this reason Examiner continues to find the instant rejection to be valid, and respectfully requests that this rejection be upheld.

(10.02) Response to Argument: 35 U.S.C. §112, Second Paragraph.

Appellant argues that the freedom to be one's own lexicographer in the drafting of patent claims is unlimited (Brief at page 20, lines 17-20). Examiner respectfully disagrees as follows.

Appellant argues that " ... [e]xaminer has pointed to no precedent or rule that prohibits the use of the language recited in the present claims and has provide no reason or evidence as to why one skilled in the art would be unable to discern the metes and bounds of the claims."

Appellant is referred to the rejection of record at page 7 of the Office action mailed August 20, 2008 wherein an explanation of why the above noted rejection has been made has been advanced. Said explanation is supplemented by the following argument.

In claim **1** at line 3, the term "a compound comprising" is internally inconsistent because the term "a compound" is narrowly limited to single molecular species with well defined metes and bounds (see list at lines 3-8), while the term of art "comprising" (synonym of "including") implies that additional structural features are present in said "compound" (but are undefined in the claim - incompleteness), and/or that the list of compounds "includes" additional unnamed and otherwise unidentified substances which also qualify as active ingredients (incompleteness of a different kind). This explanation provides a description of the logical problems underlying the rejection of the noted term, and therefore why the noted term is unacceptable as indefinite in a patent claim.

(10.03) Response to Argument 35 U.S.C. §112, Second Paragraph.

Appellant argues that "... claim 12 does not use the term 'medical condition,' as asserted by the Examiner." Examiner has reviewed the rejection in question and the response to the rejection in the Office action mailed August 20, 2008 at pages 7-8, and has not found any basis for Appellant's assertion whatsoever. Examiner could not find the term "physical condition" defined in either medical dictionary presently available, but does not disagree with Appellant's assertion that said term has been found in many locations in the literature. However, that said term has been found in many locations does not equate with Appellant's assertion that there is one agreed upon definition for said term.

Examiner notes two definitions of the term "physical:"
i) in Stedman's Medical Dictionary (27th Edition at p. 1380, col. 1; "Relating to the body, as distinguished from the mind.") and
ii) in Taber's Cyclopedic Medical Dictionary (19th Edition at p. 1653, col. 2; "**1**. Of or pert. to nature or material things. **2**. Concerning or pert. to the body, bodily."). Examiner respectfully disagrees with Appellant's argument because the quoted definitions of the term "physical" from two established and well recognized sources of medical term definitions does not permit agreement with Appellant's argument. In particular the above definitions entirely fail to establish the distinction Appellant seeks to make, because as the included term "physical" may

be read to encompass the medically relevant biochemical process of the body as distinguished from mental processes. Because Appellant's claims seek to claim processes for influencing the biochemical processes associated with sleep, then Appellant's claimed processes are by definition "physical" because they relate to existing "bodily" functions. Therefore, according to Examiner's understanding of logic, the noted limitation is in effect negating the subject matter being claimed (i.e. a method of treatment that causes a change in one or more bodily functions is causing a change in a "physical condition"), and therefore renders the instant claimed subject matter a logical nullity.

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.04) Response to Argument 35 U.S.C. §112, Second Paragraph.

Appellant argues that the subject matter of claim **12** is not expanded by the contents of claim **13**. Examiner respectfully disagrees because the term "substance abuse disorder" implies that the method of claim **12** is directed to the treatment of not only a sleep disorder but also one or more substance abuse disorders, one possible set of underlying causes admitted by Appellant's claim **13** but not defined therein as to the intended metes and bounds. Appellant has not provided any showing that all "substance abuse disorders" have as a symptom "sleep disorders" or that the instant claimed treatment if reasonably predictably effective for all sleep disorders caused by a substance abuse disorder. For example, drinking too much water before bed time (well known to adults and to parents of small children as a "substance abuse disorder") can cause fitful sleep by the necessity of awakening in order to empty the bladder, which is in turn necessary to avoid wetting the bed, a condition not treatable by the instant claimed method, but encompassed thereby because of Appellant's insistence on including the noted functional limitation within the instant claims.

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.05) Response to Argument: 35 U.S.C. §112, Second Paragraph.

Appellant argues that the noted term in claim **19** cited in the rejection is definite because the disease condition being treated is defined with adequate definiteness. Examiner

respectfully disagrees, noting that the cited claim limitation is the third negative limitation applied to the subject matter of claim **12**, and therefore the previously noted indefiniteness of claim **12** has been compounded by the limitation added by claim **19** wherein some of the particular causes of sleep disorder to be treated are obscured by the included term "substance abuse disorder," a generic term that the claims fail to define with adequate particularity the metes and bounds of what substance abuse disorders are included therein. Therefore, claim **19** cannot be expected to define with adequate particularity what subject matter is not included within the metes and bounds of claim **12** following application of the limitation of claim **19**.

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.06) Response to Argument: 35 U.S.C. §112, Second Paragraph.

Appellant has argued that this ground of rejection is inappropriate because " [i]t appears that... Examiner equates an abnormal sleep/wake cycle with insomnia." Examiner respectfully disagrees with this statement because the rejection being debated herein has been made on the basis that the terminology of the claim is indefinite because "insomnia" is, by definition, included within said claimed subject matter, and that the treatment directed to "normalizing the sleep/wake cycle" appears to be overlapping with, and therefore inseparable from, a method of treatment of insomnia based on the definition of "insomnia" found in the medical dictionary cited in the rejection of record. Therefore, Appellant's attempt to exclude "insomnia" is ineffective because the only way to effectively do this is to add a limitation that specifies the cause or causes actually being treated by the claimed treatment, an alternative that Appellant has failed to exercise, and a change that would eliminate the need to rely on multiple negative limitations.

At page 26 of the Brief, in the first paragraph Appellant asserts that "insomnia" is not the only sleep disorder, nor is it an element of every sleep disorder," an assertion that avoids the reality noted above that the instant claims have failed to avoid the overlap of "insomnia" with the asserted disease condition being treated. At page 26 of the Brief, second paragraph, Appellant appears to have engaged in a clever bit of circular logic, and concludes that although "insomnia" is inherently included within the scope of the preamble terminology, Appellant can

avoid the problem by asserting the contrary, when in reality the instant claims are only enabled for the treatment of disorders of test subjects afflicted with an addiction. .

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.07) Response to Argument: 35 U.S.C. §112, Second Paragraph.

Appellant argues that the claims are adequately defined apparently on the basis that Appellant's definition of terms is to be accepted at face value without question. Examiner respectfully disagrees with Appellant's analysis because, as noted above, the treatment appears to be solely directed to amelioration of the symptoms of drug addiction, in particular cocaine and/or alcohol addictions, but does not appear to be directed to treatments leading to the normalization of the sleep/wake cycle, treating a sleep disorder, or increasing cognitive function in any non-addicted host.

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.08) Response to Argument: 35 U.S.C. §112, Second Paragraph.

Appellant has noted the previous submission of an NIH publication that addresses some causes of "problem sleepiness." This publication has been reviewed by Examiner, but said review did not reveal, or otherwise reference, the effects of the drug "cocaine" on the mammalian sleep/wake cycle, sleep disorders or cognition in sleep-deprived cocaine addicts, and therefore said publication is found to be of only incidental relevance to the instant claims, claims that are enabled solely by exemplifications wherein examiner, in an abundance of caution, must assume that the effects and/or side effects of cocaine addiction present in the tested hosts as the fundamental causative problem in each and every test subject, a reality that from Examiner's perspective casts serious doubt on the applicability of the term "problem sleepiness" as an accurate description of the condition being treated.

For the above reasons Examiner respectfully disagrees with Appellant's conclusions *in re* the definiteness of the noted term and argues that the instant rejection should be upheld.

(10.09) Response to Argument: Obviousness-type Double Patenting.

Appellant argues beginning at page 30 of the Brief that the **Renshaw et al. '703** reference is not properly considered as a citable patent for the purpose of an obviousness-type double patent rejection. However, Appellant does admit that the patented claims of the **'703** reference are properly considered to be an effective treatment of "cognitive impairment." Additionally, a simple reading of the instant claims identifies cocaine as one of the causative factors that may be present for the instant methods of treatment claims to be effective in improving the cognitive functioning of a sleep impaired host. In view of the fact that the tested hosts in the instant specific embodiments are all cocaine addicted individuals (see Tables 1-2 in the **'703** patent at columns 5-6), it seems to be a reasonable deduction that the cocaine-addiction-ameliorating effects of CDP-choline and related compounds as described in the **'703** patent inherently possess the capability to effectively treat sleep disorders in the same cocaine addicts, and therefore that the instant claimed subject matter is inherently included within the effects caused by the administration of CDP-choline to cocaine addicts, including cocaine addicts that are sleep deprived wherein said sleep deprivation is a direct consequence of said cocaine addiction. This view appears to have been confirmed by the disclosure of the **'703** reference which states at column 3, lines 10-13, that cocaine consumption is in part due to " ... use [of cocaine]... to prevent withdrawal symptoms." Claims ***5 and 6*** of said patent are directed in part of claim ***5*** to a "method of preventing or ameliorating stimulant-induced cerebral vasoconstriction sequelae" and is further defined in claim ***6*** as being associated with the symptoms of "a vegetative response" or "motor activity impairment," terminology that, when taken together, appear to teach the administration of CDP-choline to prevent or ameliorate at least one of the symptoms of withdrawal from cocaine dependence, i.e. "sleepiness." The symptoms quoted above from claim ***6*** of the **'703** patent are notoriously well known as characteristic of "sleepiness" and of the other similarly "sleepiness-related" descriptive terms presented in preambles in the instant claims.

For confirmatory purposes Examiner also has consulted with "The Merck Manual of Diagnosis and Therapy, 18th Edition," at Chapter 198 under the heading "COCAINE," wherein said reference at page 1693, column 2, last three lines, states the following: "[t]olerance to cocaine occurs, and withdrawal from heavy use is characterized by somnolence, increased appetite, and depression" (emphasis added). Webster's Dictionary defines "somnolence" as "the quality or state of being drowsy, sleepiness." These definitions appear to confirm Examiner's view that the instant claims are directed in effect to the treatment of

cocaine withdrawal, including the symptom of "sleepiness" or "somnolence," and therefore that the instant claims and the claims of the **'703** reference have been correctly determined to be directed to overlapping subject matter.

Therefore, Examiner respectfully concludes that the instant claims, like those in the **'703** patent, are directed to the treatment of the symptoms of cocaine dependence, including the symptoms associated with the withdrawal therefrom. The term "a stimulant induced disorder" is found in the preamble of claim ***1*** of the **'703** patent. Although the **'703** patent does not specifically mention the treatment of sleepiness, sleep disorders, or the other symptoms present in the preambles of the instant independent claims, the **'703** patent is found to inherently include all of the instant treatment-directed subject matter as variations that would have been obvious to the ordinary practitioner familiar with the symptoms of both cocaine dependence and the process of withdrawal therefrom. This conclusion is found to support the maintenance of both the instant obviousness-type double patent rejection and the subsequent rejection under 35 U.S.C. §103(a).

For the above reasons Examiner respectfully disagrees with Appellant's arguments and conclusions *in re* the obviousness of the noted claims and argues that the instant rejection should be upheld.

(10.10) Response to Argument: Obviousness under 35 U.S.C. §103(a).

Appellant is referred to the response immediately preceding wherein the merits of the instant obviousness rejection have been argued simultaneously with the response to Appellant's arguments in opposition to the obviousness-type double patent rejection.

For the above reasons Examiner respectfully disagrees with Appellant's arguments and conclusions *in re* the obviousness of the noted claims and argues that the instant rejection should be upheld.

(11) Related Proceeding(s) Appendix.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiners' answer.

For the above reasons, it is believed that the rejections should be sustained.

LECrane:lec
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Respectfully submitted,

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